

**National Pharmaceutical Pricing Authority**

**Subject: Minutes of the 1<sup>st</sup> meeting of Multidisciplinary Committee of Experts held on 16.4.2018 at 11:00 AM in NPPA**

1<sup>st</sup> meeting of the "Multidisciplinary Committee of Experts" was held on 16.4.2018 under the Convenorship of the Sh. Kalyan Nag, Adviser (Cost), in the Conference Room of NPPA. The following members/officers attended the meeting:-

1. Dr. Saranjit Singh, Professor & Head, NIPER, SAS Nagar (Member)
2. Dr. Vijay Kumar, Scientist G & Head (BMS), ICMR, New Delhi (Member)
3. Sh. A P S Sawhney, Director (Pricing), NPPA
4. Sh. Baljit Singh, Assistant Director (Pricing), NPPA
5. Sh. Prasenjit Das, Assistant Director (Pricing), NPPA

At the outset, the Convenor extended warm welcome to the members and explained to them the purpose of the Committee, as mandated in DPCO 2013. The members were provided a copy of DPCO, agenda papers, and also all other supporting documents. The salient features of DPCO 2013 were also deliberated, it being the first meeting.

The members of the Committee then first took up agenda under para 11(3&4) of DPCO, 2013. The item-wise deliberation and decision are given as under:

A. Agenda relating to Para 11(3) of DPCO 2013.

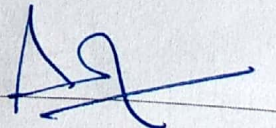
**Agenda No. A.1 Review order no.31015/08/2017-Pricing dated 30.10.2017 Review order in respect of Timolol Drops 0.5% Eye Drops filed by M/s Sun Pharma Laboratories Ltd.**

The Committee deliberated the issue and noticed that the applicant has not submitted documents/explanations in support of their claim. Accordingly, the Committee directed NPPA office to get the detailed justification alongwith the following documents/ information from the applicant:

- I. Details of superiority/therapeutic rationale of Timolet OD and Timolet GFS, if any, with respect to their other products.
- II. Copy of the licences of all the four products of the applicant with their launch date.
- III. The name of other products available in the market similar to Timolet OD and Timolet GFS, alongwith the copy of their packshots.
- IV. Original samples of all the four products of the applicant alongwith copies of the marketing literature.

**Agenda No. A.2 Review order no.31015/25/2017-Pricing dated 30.10.2017 Review order in respect of Methylprednisolone 40mg/ml Injection filed by M/s Cadila Healthcare Ltd**

The Committee deliberated the issue in detail and noted that while implementing the review order of M/s Pfizer Ltd, the only 5 ml pack of the subject formulation was excluded for working out the revised ceiling price of two pack sizes i.e., 1 ml and 2 ml. Further, the



Committee also observed that in Indian Pharmacopoeia (IP 2014) the dose of Methylprednisolone has been mentioned as 40 mg to 120 mg and, therefore, 2 ml pack cannot be considered as a multi-dose pack. Hence, the Committee did not agree with the contention of the applicant for separate ceiling price for 1 ml and 2 ml packs also.

The Committee deliberated on the issue regarding separate pricing of Methylprednisolone suspension and powder for injection, and observed that Methylprednisolone Succinate (USP) is a water soluble salt of Methylprednisolone and, therefore, it is marketed as Powder for injection. Methylprednisolone acetate is suspension form of injection and hence it is a depot product. The contention of the company has been that their formulation is not a conventional formulation but an advanced release formulation. This needs detailed justification in comparison to other depot products available in the market. Accordingly, the Committee directed NPPA office to get the detailed justification from the applicant.

**Agenda No. A.3 Review order no. 31015/61/2017-Pricing dated 11.01.2018 Review order in respect of Sodium Valproate Tablet 200 mg filed by M/s Sun Pharmaceutical Industries Ltd.**

The Committee deliberated the issue in detail and noted that "Encorate Chrono 200 mg tablet" contains combination of sodium valproate 133.33 mg and valproic acid 58 mg tablet, and corresponds to sodium valproate 200 mg tablet formulation. This is also mentioned in the label of the product of the applicant. Most other products have also label claim of sodium valproate 200 mg. It recognized that the Encorate Chrono 200 mg tablet has valproic acid (active moiety) along with its sodium salt. The committee took note of NLEM Committee recommendation that "The NLEM Committee decided that in general, medicines should be mentioned in the NLEM in terms of their active moieties, without mentioning the salts. However, in case, where, the different salts of a medicine have significant difference in potency/pharmacokinetics/ pharmacodynamics/ efficacy-safety profile, the medicine has been mentioned in the list with respect to its specific salt." In case of this drug, sodium valproate is already mentioned in the NLEM list and so is the label claim of the company. So having combination of valproic acid (active) and sodium valproate (sodium salt) together in one tablet doesn't qualify for differential pricing structure. Accordingly, the Committee found that note (i) "The formulation of Sodium Valproate includes combination of Sodium Vaproate and Valporic Acid both together corresponding to Sodium Valproate of the stated strength" of the SO.1569(E) dated 15.5.2017 was rightly stated and is in order.

**Agenda No. A.4 Review order no.31015/14/2017-Pricing dated 11.01.2018 Review order in respect of Omeprazole 20mg tablets filed by M/s Cadila Healthcare Ltd.**

The Committee deliberated the matter and noted that all the products considered in ceiling price fixation contain Omeprazole magnesium, including the product of the applicant, i.e., OCID QRS as claimed by the company. The committee further took note of NLEM Committee recommendation that "The NLEM Committee decided that in general, medicines should be mentioned in the NLEM in terms of their active moieties, without mentioning the salts. However, in case, where, the different salts of a medicine have significant difference in potency/ pharmacokinetics/ pharmacodynamics/ efficacy-safety profile, the medicine has been mentioned in the list with respect to its specific salt. The Committee also considered that in case a medicine is available in more than one salt without any significant difference

in above aspects, it is implied that all salts of that medicine with specified dosage form and strength are considered included in NLEM, 2015.

For example, diclofenac is available as diclofenac sodium or diclofenac potassium. However there is no significant difference in the above mentioned aspects, between the two salts. Hence only diclofenac is mentioned in the NLEM, which implies that both diclofenac sodium and diclofenac potassium are included in the NLEM."

Based on the above, the committee recommended that the formulation Omeprazole Tablet includes the Omeprazole magnesium tablet of specified strength. Accordingly, the claim of the applicant cannot be considered.

**Agenda No. A.5 Review order no.31015/86/2017-Pricing dated 26.02.2018 Review order in respect of Ciprofloxacin 500 mg tablets filed by M/s Sun Pharmaceutical Industries Ltd.**

The Committee deliberated the issue and noticed that the applicant has not submitted documents/ explanations in support of their claim. Accordingly, the Committee directed NPPA office to get detailed justification alongwith the following documents/ information from the applicant:

- I. Details of superiority/therapeutic rationale of Cifran OD tablet, if any, with respect to their other products.
- II. Copy of the licences of all the products of this formulation of the applicant with their launch date.
- III. The name of other products available in the market similar to Cifran OD tablet alongwith the copy of their packshots.
- IV. Original samples of all the products of the applicant alongwith the copies of the marketing literature.

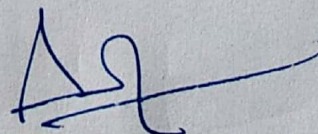
**Agenda No. A.6 Review order in respect of Ringer Lactate Injection filed by Aculife Healthcare Private Ltd (Review Order No. 31015/81/2017-Pricing dated 21.03.2018), Albert David Ltd (Review Order No. 31015/76/2017-Pricing dated 21.03.2018), B.Braun Medical (India) Pvt. Ltd (Review Order No. 31015/84/2017-Pricing dated 21.03.2018), Fresenius Kabi India Private Ltd (Review Order No. 31015/82/2017-Pricing dated 21.03.2018) and Otsuka Pharmaceutical India Private Limited (Review Order No. 31015/79/2017-Pricing dated 21.03.2018).**

The Committee noted the matter and directed NPPA office to direct all the applicants to give demonstration on a suitable date in the meeting of the Committee.

**B. Agenda relating to Para 19 of DPCO 2013**

**Additional Agenda No B.1:** The committee also discussed the applications of Boston Scientific Pvt Ltd. and M/s Medtonic Pvt Ltd for upward revision of the ceiling price/retail price under para 19 in respect of coronary stents. The committee directed that a demonstration/presentation by the concerned companies before the multidisciplinary committee to be fixed on a suitable date. The Committee also directed an interventional cardiologist preferably from AIIMS, New Delhi may be invited as special invitee in the said meeting.

**C. Cases relating to para 15(3) of DPCO 2013**



**Agenda C.1 to C.22 of Pharmacoeconomics.** : Due to paucity of the time, the committee decided to defer the pharmacoeconomics to the next meeting.

The Committee noted that Dr. Bangarurajan, Jt Drug Controller from the Office of CDSCO was not able to attend the meeting due to pre-occupation and requested the Convenor to impress upon all the members to attend all the Committee meetings in future to contribute their valuable inputs during proceedings of the meeting.

**Agenda No. 9 Co-option of other members of the Committee (With the permission of Convenor).**

In view of the technicalities of the issues brought before the Multi Disciplinary Committee, it has been decided by the committee to co-opt following members as co-opted members:

- I. Representative from Indian Pharmacopeia Commission (IPC), Rajnagar, Gaziabad.
- II. Pharmacology expert.
- III. Representative from NLEM Committee constituted by M/o Health and Family Welfare.

The Committee further directed NPPA office to write to Secretary-cum-Scientific Director, IPC and Secretary, Ministry of Health and Family Welfare for nominating a suitable representative from their respective organization/office as co-opted members as stated above in the Multi Disciplinary Committee. As regard pharmacology expert, names of Dr. C.D. Tripathi, Head of Department, Pharmacology, Safdarjung Hospital or Dr. C.S. Gautam, Head of the Department of Pharmacology, Government Medical College & Hospital, Sector 32, Chandigarh were suggested with the direction that NPPA office may seek their consent before co-opting as member to Multi Disciplinary Committee.

2. It was resolved to meet again at an early date to attend to the agenda that was left out.
3. The meeting ended with a vote of thanks to the Chair.



(A. P. S. Sawhney )

Director (Pricing)

Copy to:

All members of the Standing Committee